

have comparable cycles for both strategies a three-year time horizon was used for cost comparison. Total screening costs were 26% lower for HPV genotyping and only 21% higher for treatment costs, resulting in total savings of 1.6 million over cytology. **CONCLUSIONS:** Compared to cytology, incorporation of cobas HPV genotyping test as primary screening for CxCa at IMSS represents during the first-cycle potential savings of 10% as an improvement in clinical benefits, such as reduction in the incidence and mortality due to CxCa.

#### PMD6

##### EXHALED NITRIC OXIDE FOR THE DIAGNOSIS OF ASTHMA IN ADULTS AND CHILDREN: A SYSTEMATIC REVIEW

Harnan S<sup>1</sup>, Essat M<sup>1</sup>, Gomersall T<sup>1</sup>, Tappenden P<sup>1</sup>, Wong R<sup>1</sup>, Lawson R<sup>2</sup>, Pavord I<sup>3</sup>, Everard M<sup>4</sup>

<sup>1</sup>University of Sheffield, Sheffield, UK, <sup>2</sup>Royal Hallamshire Hospital, Sheffield, UK, <sup>3</sup>Oxford University, Oxford, UK, <sup>4</sup>The University of Western Australia (M561), Australia, Australia

**OBJECTIVES:** The fraction of exhaled nitric oxide (FeNO), a marker of eosinophilic inflammation, may be a useful diagnostic test in asthma. This systematic review aimed to identify and synthesise evidence relating to the diagnostic accuracy of FeNO for asthma. **METHODS:** Systematic searches of nine key biomedical databases and trial registers (including MEDLINE, EMBASE, the Cochrane library and clinicaltrials.gov) were carried out to November 2014. Records were considered by one reviewer and included if they: recruited patients presenting with the symptoms of asthma; used a single set of criteria (i.e. not case-control); measured FeNO in accordance with American Thoracic Society guidelines, 2005 (off-line measurements excluded); reported/allowed calculation of true positive, true negative, false positive and false negative patients as classified against any reference standard. Study quality was assessed using QUADAS II. Data was extracted by one reviewer using a standardised form and checked by a second. Meta-analysis was planned where clinical study heterogeneity allowed. Rule-in and Rule-out uses of FeNO were considered. **RESULTS:** 4865 records were identified and 32 studies were included. 5 studies recruited children and/or adolescents, and 27 studies recruited mixed ages or adults. Studies were sub-grouped by study characteristics. Heterogeneity precluded meta-analysis. Cut-off values for the best sum of sensitivity and specificity varied from 12ppb to 55ppb, being generally lower in children. Results varied, but the highest sum of sensitivity and specificity was reported for patients with chronic cough using a reference standard of airway reversibility testing (sensitivity 90% and specificity 85%). 100% sensitivity or 100% specificity were reported by some studies indicating potential use as a rule-in or rule-out strategy. **CONCLUSIONS:** FeNO has variable diagnostic accuracy even within subgroups of studies with similar characteristics. However, FeNO could be informative within a diagnostic pathway involving other tests. Cut-off values should probably be lower in children.

#### PMD7

##### HEALTH OUTCOMES EVALUATION OF NEW TECHNOLOGIES IN CLINICAL PRACTICE: THE CASE OF THE MINIMALLY INVASIVE INSERTABLE CARDIAC MONITOR

Venturini F, Magri MR, Ambrosini F, Lodi MC, Politano C, Lombardi F

Maggiore Policlinico Hospital Ca' Granda Foundation, Milano, Italy

**OBJECTIVES:** The Medical Devices Committee (MDC) of the Maggiore Policlinico Hospital in Milan, Italy, approved the use of a minimally invasive insertable cardiac monitor (ICM). ICMs are leadless subcutaneous devices that continuously monitor the heart rhythm and record events, allowing for the diagnosis of infrequent rhythm abnormalities that can be the cause of palpitations, syncope and stroke. Given the limited available literature and foreseen increase in expenditure, the MDC established an outcome monitoring process in order to test the effectiveness of the device in real practice in detecting abnormal heart rhythms and therefore diagnose and implement a timely appropriate treatment. **METHODS:** According to the literature, available guidelines and clinical opinion, four groups of patients would potentially benefit from the ICM insertion: patients with syncope of unknown etiology, myocardial infarction (e.g., arrhythmia risk stratification after the event), relapsing arrhythmia after transcatheter ablation of atrial fibrillation (AF) and cryptogenic stroke. A standardized data collection form was developed for requesting the device to the hospital pharmacy, including patient's characteristics and clinical condition for use. A follow up report describing clinical outcomes (e.g. detected arrhythmias, time to event, diagnostic formulation) needs to be provided every 6 months. **RESULTS:** From 7/2014 to 5/2015, the ICM was implanted in 14 patients. The average patients' age at the time of insertion was 54.8 years (range: 27–84 years). 78.6% of patients (11) showed syncope of unknown etiology, 14.2% (2) suffered a cryptogenic stroke, while 1 patient (7.1%) received transcatheter ablation of AF with possible anticoagulant antiarrhythmic therapy suspension. A final diagnosis was reached for 5 (36%) patients; in particular, for 2 a sustained arrhythmia was detected within 15 days since the implant. **CONCLUSIONS:** The inclusion in clinical practice of a new technology has increased the expenditure for medical devices. However, the forthcoming availability of clinical outcomes will document whether the diagnosis process has been improved.

#### PMD8

##### PUBLISHED DIAGNOSTIC DISCORDANCE OF LYMPHOMA AND POTENTIAL FOR IMPACT ON PATIENT CARE

Heinrich K<sup>1</sup>, Smallwood C<sup>2</sup>

<sup>1</sup>Becton, Dickinson and Company, Franklin Lakes, NJ, USA, <sup>2</sup>Becton, Dickinson, and Company, Mississauga, ON, Canada

**OBJECTIVES:** To determine the published frequency of diagnostic discordance leading to potential mismanagement of patient treatment for lymphoma by meta-analysis. **METHODS:** A systematic literature search using PubMed database was conducted from 2000 to May 2015. Literature was restricted to articles published after 2000, the year the World Health Organization classification of hematologic malignancies was published. The search string used was: ((((((pathology) OR diag-

nosis)) AND discordance[Title/Abstract]) AND lymphoma)) OR ((lymphoma[Title]) AND pathology[Title]). The pooled major discordance frequency was calculated using Neyeloff, Fuchs and Moreira's Excel random effects model (2012). Weighted averages using a random-effects model are reported with 95% confidence intervals with continuity correction. **RESULTS:** Eight (8) articles evaluating and differentiating minor and major second-opinion discordance in lymphoma diagnosis were included in this study. Major discordance is defined as diagnostic discrepancy between the preliminary or final diagnosis and second-opinion review that is determined by the study authors could have an impact on patient management. The proportion of discordance that was major ranged from 4.27% to 20.00%. The pooled proportion of major discordance was 9.10% (95% CI 5.86%-12.35%) in a pooled sample of 5,322 lymphoma patients. Only 1 study, a published abstract, analyzed the actual patient impact of discordant pathological results through chart review, determining 2.9% of patients were over-treated, under-treated, had significant change in treatment or incorrect treatment due to diagnostic error (Kukreti et al., 2006). **CONCLUSIONS:** Diverse methodologies led to considerably variable estimates; however, this meta-analysis revealed that an estimated 9.10% of lymphoma diagnoses could be incorrect to the point of impacting patient treatment management.

#### PMD9

##### THE CONSEQUENCES OF REPLACING THE FLEISCHNER GUIDELINES BY A SOFTWARE-BASED VOLUME DOUBLING TIME TECHNIQUE: AN EARLY-STAGE RESEARCH

Schoutrop A<sup>1</sup>, Broekhuizen H<sup>1</sup>, Siesling S<sup>2</sup>, Jzerman MJ<sup>1</sup>

<sup>1</sup>University of Twente, Enschede, The Netherlands, <sup>2</sup>Comprehensive Cancer Centre the Netherlands (IKNL), Enschede, The Netherlands

**OBJECTIVES:** Currently various diagnostic pathways for incidentally detected pulmonary nodules are used and it is not clear which diagnostic pathway should be used to potential lung cancer. An early diagnosis of a possible malignancy in the lung is important in order to increase the survival chance of the patient. In this study the regular used Fleischner Recommendations are compared with a software based volume doubling time (VDT) technique. **METHODS:** A model of the two possible diagnostic pathways is developed and built in R. The used incidence rates of pulmonary nodules and lung cancer are obtained from literature. The primary endpoint is the incidence rate of lung cancer after one year. Secondary endpoints are the test results of the diagnostic pathways. Ten thousand patients were included in order to decrease bias and increase precision of the model. **RESULTS:** Diagnosis with help of VDT led to a lower rate of false positives and false negatives, compared to the Fleischner Recommendations. Furthermore, €188.394,66 was saved in the simulation when VDT was used. The sensitivity of VDT could decrease with 7 percent in order to be as good as Fleischner Criteria, and was still cheaper. **CONCLUSIONS:** The replacement of the Fleischner Recommendation by software based VDT can lead to a decrease in false positives and false negatives. Since the total costs of VDT are lower than the costs of the Fleischner Recommendation also a reduction in health care costs is possible. However, since this was an early-stage research more direct evidence should be collected in the future.

#### PMD10

##### ASSESSING THE CLINICAL AND ECONOMIC IMPACT OF AN AUTOMATED, ON-DEMAND IMMUNOASSAY FOR THE DIAGNOSIS OF HEPARIN INDUCED THROMBOCYTOPENIA

O'Brien EC, Pannelay AJ, Caton S

Bazian Ltd, EIU Healthcare, London, UK

**OBJECTIVES:** To understand and quantify the clinical and economic impact of an automated, on-demand diagnostic test versus current diagnostic tests, for heparin-induced thrombocytopenia (HIT). **METHODS:** A mixed methods study combining a literature review with primary research. The literature review searched multiple databases to identify data on test performance, clinical and economic data. Semi-structured interviews (n=4) provided insight into current practice and challenges faced, validated by a larger survey (n=90). Two flow diagrams modelling a hypothetical cohort of 1000 patients were used to calculate the clinical and cost impact of automated, on-demand testing. **RESULTS:** The automated, on-demand test had comparable or lower sensitivity, and a higher specificity than other available tests. Clinical data and survey findings indicate that the specificity of the most widely used antibody tests (ELISA) is suboptimal. The survey revealed that half of patients are speculatively switched off of heparin and onto replacement therapy based on clinical assessment alone, rather than based on clinical assessment and diagnostic test results as per guideline recommendations. Speculative treatment is driven by test turnaround time of >24 hours for >50% of respondents. The cost model indicated that the cost of replacement therapy whilst awaiting test results of >24 hours' turnaround time was between \$7215 and \$31268. Automated, on-demand antibody testing and switching patients off heparin based on test results reduced this cost to between \$2737 and \$13092. **CONCLUSIONS:** Automated, on-demand HIT antibody testing could enable physicians to use timely diagnostic test results with better specificity than current tests to make treatment decisions. This could potentially enable earlier treatment of HIT to reduce complications such as extended hospitalisation and death, thus improving clinical outcomes and reducing costs. Also, earlier informed treatment decisions could yield pathway cost reductions through reducing the use of replacement therapies in non-confirmed and false positive cases.

#### PMD11

##### ANALYSIS OF BREAST CANCER PATIENTS' CLINICAL PATHWAY BEING DIAGNOSED BY MAMMOGRAPHY BREAST SCREENING PROGRAM

Laczó A<sup>1</sup>, Péter I<sup>2</sup>, Endrei D<sup>3</sup>, Cs Horváth Z<sup>4</sup>, Sebestyén A<sup>5</sup>, Boncz I<sup>3</sup>

<sup>1</sup>National Healthcare Service Center, Pécs, Hungary, <sup>2</sup>Szigmondy Vilmos SPA Hospital, Harkány, Hungary, <sup>3</sup>University of Pécs, Pécs, Hungary, <sup>4</sup>Government Office of Baranya County, Pécs, Hungary, <sup>5</sup>National Health Insurance Fund Administration, Pécs, Hungary